

### **REMARKS/ARGUMENTS**

Claims 1, 3-7, 9-21 and 24-25 were pending at the time of the mailing of the outstanding Office Action. By this amendment, new claims 26 and 27 have been added. No claims have been amended or cancelled.

In the Office Action of 28 October 2009, claims 1, 3-7, 9-20 and 24-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot (U.S. Pat. Pub. No. 2003/0236567, hereinafter "Elliot") in view of Collombel et al. (U.S. Pat. No. 5,166,187, hereinafter "Collombel") and Kuo et al. (U.S. Pat. No. 6537,979, hereinafter "Kuo"). Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot/Collombel in view of Kuo and Swan (U.S. Pat. No. 5,563,056, hereinafter "Swan"). Claims 1, 3-7, and 9-20 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen (U.S. Pat. No. 6,685,626, hereinafter "Wironen") and Collombel in view of Kuo. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen/Collombel in view of Kuo and Swan.

In the Office Action, it was maintained that Elliot teaches an implantable prosthesis which can be used to replace a portion of, or to be used within, a body passageway and being composed of a metal and being coated with materials susceptible to tissue ingrowth such as hyaluronic acid and chitosan. It was also indicated that Elliot does not teach a coating composition in which the rate of degradation of the polysaccharide layer is slowed from the outside toward the main body of the implant, or where a single layer is composed of hyaluronic acid and chitosan. It was additionally maintained in the Office Action that Collombel teaches the usage of chitosan as a prosthesis coating and that the rate of degradation can be adjusted according to the molecular weight and degree of acetylation of the chitosan. It was further maintained that Kuo teaches a number of approaches to reduce the diffusivity of hyaluronic acid, including the use of crosslinking agents such as formaldehyde, divinyl sulfone and bis-epoxides.

To establish a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success, and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP §

2143.) Although a failure of any one of these requirements will prevent the establishment of a prima facie case of obviousness, the Applicants respectfully maintain that none of these requirements has been met.

First, one of ordinary skill in the art would not have found a teaching or motivation to combine the references as suggested in the Office Action. While Elliot (and likewise Wironen) teaches the use of coating materials such as hyaluronic acid and chitosan to encourage cell in-growth (Elliot, paragraph 0025; Wironen, column 2, lines 40-42), Kuo clearly teaches the use of a hyaluronic acid coating to prevent tissue adhesion (Kuo, column 2, lines 6-11 and 28-41, and column 4, lines 10-14, inter alia). As stated previously, Collumbel does not teach or suggest the use of a coating for an implant having a metallic main body. Collumbel provides a chitosan-containing composition primarily as an artificial skin. The only teaching or suggestion of use of a chitosan compound as a coating on an implant is in connection with silicon or Dacron prostheses to prevent slipping of the prosthesis (Example 4). One of ordinary skill in the art would not look for guidance from Collumbel regarding an implant having a metal main body.

In response to the Applicants' previous arguments, it was asserted that one of skill in the art would have been motivated to look across the literature for ways to improve the biocompatibility of chitosan and the coating of Elliot is one such method. However, there is no motivation provided by any of the cited references to search for any other ways to improve the biocompatibility of chitosan or hyaluronic acid, since no defect associated with the biocompatibility of either compound is taught. Furthermore, the conflicting teachings regarding the use of the implant coatings of Elliot and Kuo are not resolved by any teaching of Collumbel regarding the non-implant use of a chitosan-containing material. Additionally, one of ordinary skill in the art, reading Kuo, would have known that prevention of cell adhesion could be accomplished by decreasing the amount of crosslinking in the hyaluronic acid. Such a person would have had no motivation to add chitosan to a coating as claimed. The Applicants maintain that the suggestion to combine the references as asserted is only the result of impermissible hindsight.

As stated in a previous response, the Applicants maintain that the degradation of a polymer component would be undesirable as taught by Elliot. Elliot provides a prosthesis which is intended "to replace a portion of a bodily passageway" (paragraph 0020) to treat

conditions such as abdominal aortic aneurysm (Abstract). As such, degradation of the prosthesis could cause leaks or even failure of the prosthesis, which would be highly undesirable (see paragraph 0006). In the most recent Office Action, it was countered that Elliot mentions mechanical failure based on excessive wear at a metal interface not a failure of leaking based on a coating layer degradation. However, while this is discussed as one potential source of leakage, it is not the only cause of leakage provided by Elliot. The Applicants wish to call specific attention to paragraph 0006 and Fig. 1, which clearly references a hole 6 torn in prosthesis 2. Therefore, Elliot teaches away from the desirability of any degradation by any part of an implant. As before, the teachings of Collumbel do not resolve the conflict between the remaining references.

Furthermore, given the conflict between the properties of the implant coatings of Elliot and Kuo, one of ordinary skill in the art would have had no reasonable expectation of success in combining the references as suggested with the teachings of Collumbel regarding a non-implant use of chitosan-containing material.

Finally, even if one of ordinary skill in the art were to overlook the deficiencies noted above, the references do not teach or suggest all the claim limitations. None of the cited references teach or suggest a non-uniform degradation rate of the coating as claimed. While Elliot (and Wironen) aim to improve cell adhesion in an implant, Kuo aims to decrease it. There is no teaching or suggestion in the cited prior art or in the knowledge available to one of ordinary skill in the art, that there would be any benefit to an implant coating in which the outer parts of the coating prevent cell adhesion by a fast degradation rate while cell adhesion is supported by the slowed degradation of inner parts of the coating.

For the reasons provided above, the Applicants maintain that independent claims 1 and 13 patentably distinguish over Elliot, Collombel and Kuo, either individually or in combination. Likewise, claims 3-7, 9-12, 14-20 and 24-25, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Elliot, Collombel and Kuo. Withdrawal of the rejection of claims 1, 3-7, 9-21 and 24-25 under 35 U.S.C. § 103(a) as unpatentable over Elliot in view of Kuo and Collombel is requested.

Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot/Collombel in view of Kuo and Swan. The comments provided above regarding Elliot,

Collombel and Kuo are repeated herein with respect to this rejection of claim 21. Swan was cited as providing immobilization techniques in a three-dimensional, cross-linked matrix. Swan does not however, provide the missing motivation or suggestion to combine the references noted above, or the missing elements of the claims. Therefore, the Applicants maintain that claim 21 also patentably distinguishes over Elliot, Collombel, Kuo and Swan. Withdrawal of this rejection of claim 21 under 35 U.S.C. § 103(a) is also requested.

Claims 1, 3-7, and 9-20 were rejected as being obvious over Wironen and Collombel in view of Kuo. Distinctions between Kuo and the present invention and between Collombel and the present invention are provided above and are repeated with regard to this rejection. As stated previously, Wironen provides a coating for a metallic implant that includes hyaluronic acid and chitosan only for a limited purpose – the creation of adhesions between implants and anatomical structures to stabilize implants. Similar to Elliot, discussed above, Wironen provides a coating designed to facilitate cell adhesion (column 2, lines 40-42). Degradation of such a layer would not facilitate the purpose of such a coating but would work against it. Kuo clearly teaches the use of a hyaluronic acid coating to prevent tissue adhesion (Kuo, column 2, lines 6-11 and 28-41, and column 4, lines 10-14, *inter alia*). As stated above, Collumbel does not teach or suggest the use of a coating for an implant having a metallic main body, but rather provides a chitosan-containing composition for use as an artificial skin. One of ordinary skill in the art would not look for guidance from Collombel regarding an implant having a metal main body.

As also stated above, there is no motivation provided by any of the cited references to search for any other ways to improve the biocompatibility of chitosan or hyaluronic acid, since no defect associated with the biocompatibility of either compound is taught. Furthermore, the conflicting teachings regarding the use of the implant coatings of Wironen and Kuo are not resolved by any teaching of Collumbel regarding the non-implant use of a chitosan-containing material. The Applicants again maintain that the suggestion to combine the references as asserted is only the result of impermissible hindsight. Furthermore, given the conflict between the properties of the implant coatings of Wironen and Kuo, one of ordinary skill in the art would have had no reasonable expectation of success in combining the references as suggested with the teachings of Collumbel regarding a non-implant use of chitosan-containing material.

Lastly, none of the cited references teach or suggest a non-uniform degradation rate of the coating as claimed. Wironen aims to improve cell adhesion in an implant, but Kuo aims to decrease it. As stated above, there is no teaching or suggestion that there would be any benefit to an implant coating in which the outer parts of the coating prevent cell adhesion by a fast degradation rate while cell adhesion is supported by the slowed degradation of inner parts of the coating.

Therefore, one of ordinary skill in the art would not have found any suggestion or motivation to combine the adjustable biodegradation properties of a compound containing either hyaluronic acid or chitosan (neither of which is disclosed as suitable for use as a coating) with an adhesion-promoting composition of Wironen to arrive at the present invention as recited in amended claims 1 or 13. The Applicants also maintain that independent claims 1 and 13 patentably distinguish over Wironen, Kuo and Collombel, either individually or in combination. Likewise, claims 3-7, 9-12, and 14-19, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Wironen, Kuo and/or Collombel. Withdrawal of the rejection of claims 1, 3-7, and 9-20 under 35 U.S.C. § 103(a) as unpatentable over Wironen in view of Kuo and Collombel is requested.

Finally, claims 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen/Collombel in view of Kuo and Swan. In light of the Applicants' comments above regarding each of these references, which are repeated with regard to the present rejection, the Applicants maintain that claim 21 also patentably distinguishes over Wironen, Collombel, Kuo, and Swan, either individually or in combination. Withdrawal of this rejection of claim 21 under 35 U.S.C. § 103(a) is respectfully requested.

New claims 26 and 27 have been added. Support for these added claims may be found in the specification in paragraphs 0022 and 0023. The Applicants maintain that the new claims also patentably distinguish over the cited prior art. Accordingly the issuance of a Notice of Allowance is earnestly solicited. The added claims bring the total number of pending claims back to 23, which was the original number of claims presented. Payment of the necessary fees for 3 claims in excess of 20 total claims was previously made. Therefore, no added fees for the new claims are believed to be due.

The outstanding Office action was mailed on 28 October 2009. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for a one month extension of time for response is believed to be due, as this response is being filed on the next business day following a period for reply that ends on a Saturday, Sunday, or federal holiday. Additionally, a conditional petition for any additional petition for an extension of time for reply is hereby made in the event that such a petition is additionally required and has been overlooked. The Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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